K091593

Section 5 – 510(k) Summary

Submitter: MEDRAD Interventional / Possis
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JUN 22 2009

Date Prepared: May 29, 2009

Trade Name: AngioJet® Ultra DVX® Thrombectomy Set
AngioJet® Ultra Xpeedior® Thrombectomy Set

Classification: 870.5150 and 870.1210

Product Code: DXE and KRA

Predicate Device(s): The subject devices are equivalent to the following devices:

- K071342 and K090253 AngioJet Ultra Xpeedior Thrombectomy Set
- K072269 and K090253 AngioJet Ultra DVX Thrombectomy Set

Device Description: AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are sterile, single use, disposable sets that include a Thrombectomy Catheter and Pump in one combined unit. The AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are used with the AngioJet Ultra Console.

Intended Use: The AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are intended for use with the Angiojet Ultra Console to break apart and remove thrombus from :

* upper and lower extremity peripheral arteries ≥ 3.0mm in diameter,
* upper extremity peripheral veins ≥ 3.0mm in diameter,
* ileofemoral and lower extremity veins ≥ 3.0mm in diameter,
* A-V access conduits ≥ 3.0mm in diameter and
* for use with the Angiojet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Functional and Safety Testing: Representative samples of the device underwent mechanical bench testing to demonstrate safety and effectiveness and appropriate functional and performance characteristics.

Conclusion: MEDRAD Interventional / Possis considers the AngioJet Ultra DVX and Xpeedior Thrombectomy Sets to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2009

Mr. Doug Atkins
Sr. Regulatory Affairs Associate
MEDRAD Interventional/Possis
9055 Evergreen Boulevard, NW
Minneapolis, MN 55433-8003

Re: K091593
Trade/Device Name: AngioJet Ultra DVX Thrombectomy Set
and AngioJet Xpeedior Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE, KRA
Dated: May 29, 2009
Received: June 2, 2009

Dear Mr. Atkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091593

Device Name: AngioJet® Ultra DVX® Thrombectomy Set

Indications for Use:

The Angiojet Ultra DVX Thrombectomy Set is intended for use with the Angiojet Ultra Console to break apart and remove thrombus from :

* upper and lower extremity peripheral arteries ≥ 3.0mm in diameter,
* upper extremity peripheral veins ≥ 3.0mm in diameter,
* ileofemoral and lower extremity veins ≥ 3.0mm in diameter,
* A-V access conduits ≥ 3.0mm in diameter and
* for use with the Angiojet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Nguyen

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091593

Indications for Use

510(k) Number (if known): K091593

Device Name: AngioJet® Ultra Xpeedior® Thrombectomy Set

Indications for Use:

The Angiojet Ultra Xpeedior Thrombectomy Set is intended for use with the Angiojet Ultra Console to break apart and remove thrombus from :

* upper and lower extremity peripheral arteries ≥ 3.0mm in diameter,
* upper extremity peripheral veins ≥ 3.0mm in diameter,
* ileofemoral and lower extremity veins ≥ 3.0mm in diameter,
* A-V access conduits ≥ 3.0mm in diameter and
* for use with the Angiojet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)